DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Ethicon Endo-Surgery, Inc.
Ms. Renee Rowe
Staff Project Manager, Quality Systems & Regulatory Affairs
4545 Creek Road
Cincinnati, OH 45242

JUL 27 2015

Re: K073484
Trade/Device Name: Ethicon Endo Surgery® Sheath and Articulating External Accessory Channel
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: ODC
Dated (Date on orig SE ltr): December 7, 2007
Received (Date on orig SE ltr): December 11, 2007

Dear Ms. Rowe,

This letter corrects our substantially equivalent letter of March 10, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073484

Device Name: Ethicon Endo Surgery® Sheath and Articulating External Accessory Channel

Indications for Use:

The Ethicon Endo Surgery® Sheath and Articulating External Accessory Channel accessory product is intended for use as a supplemental conduit that attaches to an endoscope to enable improved access.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K073484

K073484

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510(k) Summary

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Company Ethicon Endo-Surgery, Inc.
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Date Prepared December 7, 2007

Device Name Trade Name: The trademark name has not yet been determined
Common or Usual Name: Endoscopes and/or Accessories
Classification Name: Endoscopes and accessories
[21 CFR 876.1500 (KOG)]

Predicate Devices LSI Endoscopic External Accessory Channel and Accessories Product (K024301)
US Endoscopy Disposable Overtube (K040835)
Olympus Splinting Tube, ST-C4 (510(k) unknown).

Indications for Use
The Ethicon Endo Surgery® Sheath and Articulating External Accessory Channel accessory product is intended for use as a supplemental conduit that attaches to an endoscope to enable improved access.

Device Description The Ethicon Endo Surgery® Sheath and External Accessory Channel is a supplemental articulating accessory channel that attaches to an endoscope to enable improved access. The sterile, single-use, disposable device is available in two (2) basic configurations: a shorter gastroscope compatible system, and a longer colonoscope compatible system.

The flexible Sheath is installed over the insertion tube of the endoscope. The Sheath contains a track (C-Channel) along which the Articulating External Accessory Channel can be can be introduced and removed without removing and re-introducing the endoscope, allowing for multiple intubations and/or specimen retrieval independent of the endoscope. The Articulating External Accessory Channel enables the use of two accessory devices simultaneously - one in the Articulating External Accessory Channel and the other in the endoscope working channel. The Articulating External Accessory Channel provides off axis articulation to off the shelf accessory devices, thereby allowing the user to more effectively direct devices to the targeted tissue.

Technological Characteristics The new device, the Ethicon Endo-Surgery® Sheath and Articulating External Accessory Channel, is similar in functionality and design to the

predicate devices. The key similarities between the Ethicon Endo-Surgery® Sheath and Articulating External Accessory Channel and the predicate devices are as follows:

- The Indications and Contraindications for Use are similar.
- All are mounted/installed external to or over the endoscope.
- The functionality of the new device and the LSI Solutions Endoscopic External Accessory Channel predicate device is similar in that both provide a supplemental accessory channel that allows for the passage of additional endoscopic instruments.
- The new device and the US Endoscopy Disposable Overtube and the Olympus Splinting Tube predicates facilitate multiple endoscopic intubations.
- The maximum width of the insertion portion of the new device is similar to the predicate devices.

The new device offers features not provided by the predicates, as follows:

- The external accessory channel of the new device is not fixed to the scope and can be introduced and removed without a need to remove or re-introduce the endoscope. The LSI Solutions Endoscopic External Accessory Channel predicate device is fixed to the endoscope and must be must be removed and re-introduced with the endoscope.
- The new device enables articulation of compatible commercially available endoscopic accessory devices for improved ability to reach the target tissue.

A comprehensive assessment of the Ethicon Endo-Surgery® Sheath and Articulating External Accessory Channel versus the predicates indicates the new features do not raise any new issues relating to safety and effectiveness.

Performance Data. Bench testing was performed to demonstrate that the new device performs as intended. Animal testing was performed to evaluate the tissue effects associated with the new device relative to the predicate devices. Device materials have been evaluated for biocompatibility and comply with the requirements of ISO 10993-1. These data, combined with intended use and design information, indicate the Ethicon Endo-Surgery® Sheath and Articulating External Accessory Channel - is substantially equivalent to the predicate devices.